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**From:** Holden, Bob [BHolden@joneswalker.com]  
**Sent:** 8/15/2018 6:18:20 PM  
**To:** Kirby, Kevin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cbb65672f6f34545be460a66ff6fa969-Kirby, Kevin]  
**CC:** Quality [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=09879eff255940b8951dc434052ea44f-Quality]; Vandenberg, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcae2b98a04540fb8d099f9d4dead690-Vandenberg, John]  
**Subject:** RE: Request for Reconsideration, RFC #17002 (chloroprene)

Mr. Kirby,

Thank you for your email. We will review your comments with our client and keep you advised.

Bob Holden

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**From:** Kirby, Kevin <KIRBY.KEVIN@EPA.GOV>  
**Sent:** Wednesday, August 15, 2018 12:40 PM  
**To:** Holden, Bob <BHolden@joneswalker.com>  
**Cc:** Quality <Quality@epa.gov>; Vandenberg, John <Vandenberg.John@epa.gov>  
**Subject:** RE: Request for Reconsideration, RFC #17002 (chloroprene)

Mr. Holden:

Thank you for your note and voice mail concerning your submitted Request for Reconsideration (RFR) #17002A. This is to confirm receipt of your RFR and to acknowledge the ongoing efforts by your consultants at Ramboll Environ, working with EPA subject matter experts, with regard to the development and evaluation of the physiologically-based pharmacokinetic (PBPK) model.

As communicated over the phone with you and your colleague last week, we recognize that the timing for PBPK model development and peer review and then subsequent EPA evaluation for its potential use in updating the chloroprene cancer potency estimate will take longer than the timeline for a decision regarding the RFR. It was for that reason I suggested withdrawing the RFR until the PBPK model development, peer review, evaluation and application (if appropriate) is completed. I recall that you opined a lack of support for this route by your client given the work that has been done to date in preparing your Request for Correction (RFC) and subsequent RFR.

With respect to the "stay" you suggested during our phone conversation, I further explored this idea with colleagues here. As you may recall, I mentioned that there is no provision for this in EPA's Information Quality Guidelines (IQG). The preliminary feedback I have received for a stay of your RFR has not been encouraging. Internal feedback suggests that the only viable options are to either withdraw your RFR and, at your discretion, resubmit an RFC at the conclusion of PBPK model development and evaluation or keep to the process outlined in the IQG where we reconsider our original response. Absent any new information to evaluate, we will be bound to reconsider EPA's response to your RFC using the science available and peer reviewed at this time.

At this juncture, in accordance with EPA's IQG, we are assembling the Executive Panel. The 90 business day period we are targeting to respond to your RFR, calculated from the July 23 submittal date, is Nov. 30, 2018. Please keep me posted should your position change in this request.

Thanks for your dedicated attention to quality information at EPA!

Kevin

Kevin J. Kirby  
Enterprise Data Architect  
US Environmental Protection Agency

OEI/OEIP/EQMD  
202 566-1656 desk

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**From:** Holden, Bob [<mailto:BHolden@joneswalker.com>]  
**Sent:** Wednesday, August 8, 2018 11:12 AM  
**To:** Kirby, Kevin <[KIRBY.KEVIN@EPA.GOV](mailto:KIRBY.KEVIN@EPA.GOV)>  
**Cc:** Henry, Elise <[EHenry@joneswalker.com](mailto:EHenry@joneswalker.com)>  
**Subject:** RE: Request for Reconsideration, RFC #17002 (chloroprene)

Kevin:

This will follow up on our conversation yesterday. I have discussed with DPE both (1) the idea of our seeking to stay EPA's review of our RFR pending the development of and submittal to EPA of the PBPK model and results, and (2) that I had informally advised you that DPE would agree a one-week suspension of EPA review activities pending a decision on whether to seek such a longer term stay. This will confirm that DPE agrees to the one-week stand down pending further review of whether to seek a stay of EPA's review of the RFR pending the PBPK model development and submittal. We will be back in touch with you on the stay issue next week. Please feel free to call if you have any questions.

Bob

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**From:** Holden, Bob  
**Sent:** Tuesday, August 7, 2018 2:10 PM  
**To:** 'quality@epa.gov' <[quality@epa.gov](mailto:quality@epa.gov)>  
**Cc:** 'kirby.kevin@epa.gov' <[kirby.kevin@epa.gov](mailto:kirby.kevin@epa.gov)>; Henry, Elise <[EHenry@joneswalker.com](mailto:EHenry@joneswalker.com)>  
**Subject:** FW: Request for Reconsideration, RFC #17002 (chloroprene)

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**From:** Holden, Bob  
**Sent:** Monday, July 23, 2018 7:45 PM  
**To:** 'quality.guidelines@epa.gov' <[quality.guidelines@epa.gov](mailto:quality.guidelines@epa.gov)>  
**Cc:** 'Orme-Zavaleta.Jennifer@epa.gov' <[Orme-Zavaleta.Jennifer@epa.gov](mailto:Orme-Zavaleta.Jennifer@epa.gov)>; 'gentry.nathan@epa.gov' <[gentry.nathan@epa.gov](mailto:gentry.nathan@epa.gov)>; 'Bahadori.Tina@epa.gov' <[Bahadori.Tina@epa.gov](mailto:Bahadori.Tina@epa.gov)>; 'fine.steven@epa.gov' <[fine.steven@epa.gov](mailto:fine.steven@epa.gov)>; 'gray.david@epa.gov' <[gray.david@epa.gov](mailto:gray.david@epa.gov)>; 'Holloman.Vincia@epa.gov' <[Holloman.Vincia@epa.gov](mailto:Holloman.Vincia@epa.gov)>; 'idsal.anne@epa.gov' <[idsal.anne@epa.gov](mailto:idsal.anne@epa.gov)>; 'thayer.kris@epa.gov' <[thayer.kris@epa.gov](mailto:thayer.kris@epa.gov)>; 'Vandenberg.John@epa.gov' <[Vandenberg.John@epa.gov](mailto:Vandenberg.John@epa.gov)>; 'yamada.richard@epa.gov' <[yamada.richard@epa.gov](mailto:yamada.richard@epa.gov)>; 'dravis.samantha@epa.gov' <[dravis.samantha@epa.gov](mailto:dravis.samantha@epa.gov)>; Henry, Elise <[EHenry@joneswalker.com](mailto:EHenry@joneswalker.com)>; Jorge Lavastida ([Jorge-Lavastida@denka-pe.com](mailto:Jorge-Lavastida@denka-pe.com)) <[Jorge-Lavastida@denka-pe.com](mailto:Jorge-Lavastida@denka-pe.com)>; Ted R. Broyles II ([Ted.Broyles@la.gov](mailto:Ted.Broyles@la.gov)) <[Ted.Broyles@la.gov](mailto:Ted.Broyles@la.gov)>; Dwana King ([dwana.king@la.gov](mailto:dwana.king@la.gov)) <[dwana.king@la.gov](mailto:dwana.king@la.gov)>  
**Subject:** Request for Reconsideration, RFC #17002 (chloroprene)

Dear Sir or Madam:

Please find attached for filing in this matter:

1. Transmittal cover letter;
2. Request for Reconsideration, RFC # 17002 (chloroprene); and
3. Exhibits thereto.

Thank you for your attention to this.

Robert Holden



**Robert E. Holden**  
*Attorney*  
**Jones Walker LLP**  
D: 504.582.8139 F: 504.589.8139  
bholden@joneswalker.com

201 St. Charles Ave, Ste 5100  
New Orleans, LA 70170  
T: 504.582.8000  
[www.joneswalker.com](http://www.joneswalker.com)

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